



## **INTRODUCTION**

This case arises from Andreas Perry's use of Defendant's drug Elidel to treat his atopic dermatitis. Andreas was just over two years old when his parents first applied Elidel cream to his arms, legs and chest at the end of April 2003. By October, Andreas was diagnosed with T-cell lymphoblastic lymphoma, an extremely rare condition for which he had no risk factors. Thus followed a grueling treatment regimen, multiple visits to the hospital, and the prospect of serious long-term health problems stemming from his cancer treatment.

Plaintiffs in this case have offered two highly-qualified experts to meet their requirements under Pennsylvania state law to provide expert testimony regarding the causation of Andreas Perry's injury. Dr. Martyn Smith, a toxicologist, and Dr. E. Anders Kolb, a pediatric oncologist/hematologist, both prepared expert reports for this case. These reports show that pimecrolimus, the active ingredient in Elidel, can cause lymphoma in humans, and that pimecrolimus did cause Andreas Perry's lymphoma. In preparing their reports, both Dr. Smith and Dr. Kolb examined a wide variety of publications, studies, and records, and both utilized the same care and methods they use in their scientific and medical endeavors.

Defendant Novartis moves for summary judgment on the grounds that plaintiffs' experts will not be accepted by this Court to testify. However, as detailed in the Plaintiffs' opposition to Defendant's motion to exclude these experts, which is being filed today under seal, Plaintiffs have demonstrated that their experts are qualified, have employed reliable methodologies, and will provide testimony that will assist the trier of fact. Therefore, Defendant's summary judgment motion must be denied.

**I. SUMMARY JUDGMENT STANDARD**

A court may grant summary judgment only when “the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). A factual dispute is “material” only if it might affect the outcome of the case. *Fisher v. Walsh Parts & Svc. Co.*, 277 F. Supp. 2d 496 (E.D. Pa. 2003). For there to be a “genuine” issue, a reasonable factfinder must be able to return a verdict (or render a decision) in favor of the non-moving party. *Perez v. Townsend Engineering Co.*, Civ. Act. No. 4:CV-05-2337, 2008 WL 614784, at \*1 (M.D. Pa. Mar. 5, 2008).

“On summary judgment, it is not the court’s role to weigh the disputed evidence and decide which is more probative, or to make credibility determinations.” *Boyle v. County of Allegheny, Pennsylvania*, 139 F.3d 386, 393 (3d Cir. 1998). When determining whether there are genuine issues of material fact, “all inferences must be drawn, and all doubts must be resolved, in favor of the non-moving party.” *Johnson v. Vane Line Bunkering, Inc.*, No. Civ. A. 01-5819, 2003 WL 23162433, at \*2 (E.D. Pa. Dec. 30, 2003). “If a conflict arises between the evidence presented by both sides, the court must accept as true the allegations of the non-moving party.” *Fisher*, 277 F. Supp. 2d 496, 500 (E.D. Pa. 2003).

To raise a genuine issue of material fact, “the summary judgment opponent need not match, item for item, each piece of evidence proffered by the movant, but simply must exceed the mere scintilla standard.” *Id.* at 501. The court may grant summary judgment “only if, after viewing all the evidence in the light most favorable to the non-movant, no jury could decide in that party’s favor.” *Id.*

## **II. ARGUMENT**

Causation is a fundamental element of each of Plaintiff's claims. Plaintiffs' case requires expert testimony to satisfy their burden with respect to both general causation and specific causation. *See DeLuca by DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 958 (3d Cir.1990) (testimony must be able to support a jury finding both (i) that the drug can produce [the injury] and (ii) that the drug more likely than not caused the [injury] in this particular case), *on remand* 791 F.Supp. 1042 (D.N.J.1992), *aff'd*, 6 F.3d 778 (3d Cir.1993), *cert. denied*, 510 U.S. 1044, 114 S.Ct. 691, 126 L.Ed.2d 658 (1994). As discussed below, Plaintiffs have met their causation requirements by offering admissible expert testimony.

### **A. Plaintiffs Have Met the *Daubert* Requirements for Expert Testimony**

As discussed in depth in Plaintiffs' Opposition to Defendant's Motion to Exclude Testimony of Plaintiffs' Experts, filed today in this Court, Plaintiffs have presented testimony sufficient to meet the requirements of Federal Rule of Evidence Rule 702, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the caselaw applying *Daubert*. In the Third Circuit, there are three major requirements for expert testimony. First, "a witness proffered to testify to specialized knowledge must be an expert." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). Second, "the expert must testify as to "scientific, technical or other specialized knowledge [that] will assist the trier of fact." *Id.* at 742. To assist the trier of fact, the knowledge must be based on a reliable scientific methodology, and it must be relevant to the case at hand. *Id.*

As detailed in their Opposition Memorandum, Plaintiffs have met their burden. Plaintiffs' experts are exceptionally well-qualified to opine on general and specific causation. Both of Plaintiffs' experts apply accepted methodologies to the scientific data in this case, in the same way they employ these methodologies in their everyday scientific and medical work. Finally, the testimony directly relates the facts of the case and will greatly assist the trier of fact.

**B. Material Issues of Fact Regarding Causation Remain,  
Precluding Summary Judgment**

Because Plaintiffs have met their causation burden, there are genuine issues of material fact regarding numerous issues in this case. Plaintiffs contend that pimecrolimus is capable of causing cancer, and did cause Andreas Perry's cancer. By meeting their *Daubert* requirements, these genuine issues of material fact remain, and summary judgment is improper.

**CONCLUSION**

Plaintiffs have met their causation requirements under Pennsylvania law. As a result, Defendant's motion for summary judgment must be denied.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 23, 2008, a copy of the foregoing was filed with the Court. These documents are available for viewing and downloading from the Court's ECF system. Service of same has been made upon all counsel of record via the Court's ECF system.

Dated: May 23, 2008

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